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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,125	08/07/2001	Didier Communi	9409/2092	3058

27495 7590 12/17/2002

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EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 12/17/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/924,125

Applicant(s)

COMMUNI ET AL.

Examiner

Ruixiang Li

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 and 26-45 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 15-22 and 29-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-14, 23, 24 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group II (claims 7-14, 23, 24, 25 (in part), and 26-28), drawn to screening methods for a candidate modulator which is a natural or synthetic peptide, or polypeptide in Paper No. 12 filed on October 1, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In view of cancellation of claim 25 by applicants and on applicants' request, the Examiner agrees that Groups II-VII set forth in the restriction requirement (Paper No. 9, April 16, 2002) be rejoined as the claims in each of Groups II-VII are the same as a consequence of cancellation of claim 25.

The requirement is made FINAL.

2. Applicants' amendment in Paper No. 8 filed on December 5, 2001 has been received. However, it has not be entered because the amendment does not correspond to the specification.
3. Applicants' amendment in Paper No. 12 filed on October 1, 2002 has been entered in full. Claim 25 has been cancelled. Claims 1-24 and 26-45 are pending. Claims 7-14, 23, 24, and 26-28 are under consideration. All other claims are withdrawn from

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further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Drawings

4. The drawings filed on December 5, 2001 are accepted by the Examiner.

Rejections—35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 7-14, 23, 24, and 26-28 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claims 7-14, 23, 24, and 26-28 are drawn to a method of screening for a candidate modulator of GPR86 activity set forth in SEQ ID NO:2. The claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility. A specific and substantial utility is one that is particular to the subject matter claimed and that identifies a "real world" context of use for the claimed invention which does not requires further research.

The instant disclosure discloses a GPR86 polypeptide set forth in SEQ ID NO: 2 and its natural ligand, ADP. The disclosure further discloses agonistic effects of ADP on IP3 accumulation in 1321N1 cells, cAMP accumulation in CHO-K1 cells, and phosphorylation of Erk1 and Erk2 proteins in CHO-K1 cells (See, e.g., Figs. 4-6).

However, such disclosure is insufficient to satisfy the utility requirement under 35 U.S.C. §101 because the specific biological functions of the GPR polypeptide are unknown. While members of GPCRs share certain characteristic structural motifs and features of signal transduction pathways, the biological function vary widely (see, e.g., Ji et al. G-protein-coupled receptors, *J. Biol. Chem.*, 273:17299-17302, 1998). Thus, without a defined biological function, one skilled in the art would not be able to recognize the specific and substantial use of the polypeptide of SEQ ID NO:2 and consequently the use of the claimed method of screening for candidate modulators of the GPR 86 polypeptide activity.

The instant disclosure also asserts that the claimed invention provides methods of diagnosing a disease or disorder characterized by dysregulation of GPR86 signaling (pages 6 to 7). The instant disclosure further asserts that the pharmaceutical composition of the present invention have applications in treatment and/or prevention of various diseases or disorders (page 9). However, these asserted utilities are not specific and substantial because they do not identify or reasonably confirm a "real world" context of use. The disclosure neither identifies the biological functions of the claimed GPR86 polypeptide nor any disorders that are associated with the claimed molecule. Clearly, further research would be required to determine the functions of the claimed molecules or to identify a disease that can be treated or diagnosed with the claimed molecules before development of methods of diagnosis and treatment. See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct.

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1966), noting that “a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”

The invention also lacks a well-established utility. A well-established utility is a specific, substantial, and creditable utility that is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material. Being a putative G-protein coupled receptor does not simply endow the polypeptide of the present invention because of the diversity of the structure and functions of the G-protein coupled receptors. No art of record discloses or suggests any specific biological activity for the claimed molecules such that another non-asserted utility would be well-established for the compounds. Since the GRP86 polypeptide does not have immediately practical application, a method of using the polypeptide for screening a modulator of the polypeptide does not have a patentable utility accordingly.

7. Claims 7-14, 23, 24, and 26-28 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections—35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 7-14, 23, 24, and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7-14, 23, 24, and 26-28 are indefinite because they recite the term, "GPR86", which should be set forth by its SEQ ID NO (SEQ ID NO:2).

Ciaims 7-14 and 26-28 recite the limitation "said second messenger assays". There is insufficient antecedent basis for this limitation in the claim. Claims 7-14 and 26-28 also recite "detecting a signaling activity". It is unclear what signaling activity applicants intend to determine.

Claims 8 and 12 recite "other cell lines". It is unclear what the metes and bounds of the term are.

Claims 7, 9, 11, 13, and 23 are indefinite because the steps of the methods do not necessarily achieve the goal set forth in the claim preamble. It is unclear how a candidate modulator is selected, determiner, and correlated to the preamble. Claims 8, 10, 26-28 depend from Claim 7, claims 12, 14, and 26-28 depend on claim 11, whereas claim 24 depend on claim 23.

The Examiner notes that a method usually has a contacting step, a detecting step, a selecting step, and a correlation step linking the detection/selection step to the goal set forth in the preamble.

Appropriate correction is required to overcome the rejection.

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10. The art cited in the PTO-892 form by the Examiner teaches the polypeptide GPR86 set forth in SEQ ID NO:2. However, the art does not teach the natural ligand for GPR86 and the instantly claimed method.

Conclusion

11. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.


Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
November 29, 2002


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SUPERVISORY PATENT EXAMINER
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